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ATTORNEY FOR PLAINTIFF, DAVID BRENNAN

UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

DAVID BRENNAN,	:	CIVIL ACTION
	:	No. 04 CV 3241 (FLW)
	:	DOCUMENT ELECTRONICALLY
Plaintiff,	:	FILED
vs.	:	
	:	
CEPHALON, INC.,	:	PLAINTIFF'S SECOND
	:	AMENDED COMPLAINT
	:	
Defendants.	:	

David Brennan, 17 Ann Drive, Mt. Laurel, New Jersey, by way  
of Complaint says:

**FIRST COUNT**  
**\_\_\_\_\_ (COMMON LAW WRONGFUL DISCHARGE)**

1. At all relevant times herein the defendant, Cephalon, Inc. (hereafter Cephalon) is a corporation with offices located at 145 Brandywine Parkway, West Chester, Pennsylvania, does business in Camden County, New Jersey and is engaged in interstate commerce.
2. At all relevant times herein, the plaintiff, David

Brennan, was employed by the defendant Cephalon, Inc.

3. At all relevant times herein, the defendant Frank Baldino, was the Chairman and Chief Executive Office of Cephalon.
4. At all relevant times herein, the defendant Richard Kaplan was the Vice President of Quality at Cephalon.
5. At all relevant time herein, the defendant Tim Sheehan was the Director of Quality Assurance at Cephalon or otherwise employed by Cephalon.
6. At all relevant times herein, the defendant Armando Cortez was the Director of Quality Assurance at Cephalon.
7. At all relevant times herein, the Defendants John Does, are one or more fictitious named individuals, persons, corporations, professional associations, and/or professional corporations, or other forms of entities, the identities of which are unknown at present, but who are liable to the plaintiff by reason of their participation in the acts of retaliation and/or discrimination, whether directly, indirectly, or in conspiracy with their co-defendants.
8. The plaintiff, David Brennan, was first employed by Cephalon on March 4, 2002.
9. The plaintiff was terminated from employment by

Cephalon on February 12, 2004.

10. Plaintiff's title at Cephalon was Compliance Auditor.
11. The defendant Cephalon's business was the manufacture, sale and/or distribution of certain drugs, which are regulated by the United State Food Drug Administration (hereafter FDA).
12. Cephalon manufacturers, sells, and/or distributes a drug called Actiq.
13. Cephalon manufactured, sold and/or distributed the drug Actiq in New Jersey and, in particular, Camden County.
14. Actiq is a potent opiod narcotic painkiller drug in flavored lollipop form designed to provide relief from pain to cancer patients.
15. Actiq is a prescription drug which is regulated by the FDA, prescribed by physicians in New Jersey, and is consumed by New Jersey citizens including in Camden County.
16. Actiq is an opiod narcotic drug and, therefore, a risk exists that it can be abused by individuals in its use, including physicians in their prescribing.
17. Actiq is an opiod narcotic in flavored lollipop form and, therefore, a risk exists that it can be inadvertently used by individuals, in particular by unknowing children.

18. Actiq is an opiod narcotic drug that is being legally and illegally abused by individuals, as a result of Cephalon's actions and/or omissions.
19. The FDA in approving Actiq for prescription distribution to the consuming patients in need of its use, conditioned such approval by requiring Cephalon to do that which is recited herein.
20. Cephalon is required by the FDA to conduct customer surveys of the top four pharmacies that sell Actiq.
21. The survey includes questions for the patient regarding the receipt of a Welcome Kit. The distribution of the Welcome Kit to each new patient is required as one condition of approval in the FDA Risk Management Program (RMP).
22. Cephalon is required by the FDA to determine if the patients are receiving the Welcome Kits. If the Welcome Kits are not being distributed as required in the RMP, Cephalon is obligated to take action to correct that deficiency. These obligations and requirements are recited in the RMP.
23. Cephalon is required to do "Point of Dispensing" monitoring as a condition of its FDA approval. Cephalon is required to spot check pharmacies to verify that they are distributing the Welcome Kits to

patients. If the Welcome Kits are not being distributed, Cephalon is obligated to address and correct that deficiency.

24. Actiq is approved for a very narrow therapeutic category.
25. The RMP is designed to assure that the drug not be marketed outside the approved use.
26. Cephalon is obligated to monitor physician prescribing.
27. Physician specialties are described as either representing appropriate patient selection or inappropriate patient selection.
28. If the ratio of prescriptions by specialties representing inappropriate patient selection exceeds fifteen percent (15%) of the total prescriptions written, Cephalon is required to report such to the FDA and is further required to conduct physician training programs for the offending physician groups.
29. The plaintiff, David Brennan, as a Compliance Auditor, at Cephalon conducted compliance audits to determine whether Cephalon was complying with FDA rules, regulations, and conditions of approval for certain drugs manufactured, sold, and or distributed by Cephalon.
30. In the first quarter of 2003, Richard Kaplan (hereafter

Kaplan), Vice President of Quality, directed the plaintiff, David Brennan, to conduct an audit of the Risk Management Program of Cephalon's drug Actiq.

31. With approval of Mr. Kaplan, the plaintiff was to begin an RMP audit of Actiq in the second quarter of 2003.
32. The plaintiff first developed an Audit Plan with input from Mr. Kaplan regarding the compliance audit of Actiq.
33. The detailed Audit Plan was based on a point by point comparison to the approved RMP document requirements for the drug Actiq.
34. In October of 2003, the plaintiff submitted a draft copy of his audit report to Mr. Tim Sheehan, Director of Quality Assurance for Cephalon.
35. The draft copy of the plaintiff's audit report submitted to Mr. Sheehan concluded that Cephalon was NOT in compliance with the Risk Management Program that was a condition of approval by the FDA for the drug Actiq.
36. The draft audit report recited that Cephalon was not in compliance with the FDA approval for Actiq's manufacturing, sale and distribution by Cephalon because of the following:
  - A) Cephalon was required by the FDA as a condition of

approval, that Cephalon conduct customer surveys of four (4) pharmacy companies that sold Actiq. Cephalon surveyed only one pharmacy company, and, therefore, was not in compliance with FDA approval.

- B) Cephalon is required by the FDA to ascertain if new patients are receiving the Welcome Kits. The limited survey disclosed that a large percentage of new patients were not receiving the Welcome Kits.
- C) Cephalon is required to take action if the new patients are not receiving the Welcome Kits. Cephalon was not taking any action to correct the deficiency; and, therefore, Cephalon was not in compliance.
- D) Cephalon was required by the FDA to do Point of Dispensing monitoring. No Point of Dispensing monitoring was conducted apart from one pharmacy company's direct patient call back surveys; and, therefore, Cephalon was not in compliance.
- E) The one pharmacy company that was surveyed disclosed that the Point of Dispensing requirement was not met. Cephalon took no action to correct this deficiency; and, therefore, is not in

compliance.

- F) Actiq is approved for a very narrow therapeutic category of patients. Cephalon is obligated to assure that Actiq is not marketed outside the approved therapeutic category of patients. Physician specialties are described as representing appropriate patient selection or inappropriate patient selection. If the ratio of prescriptions by specialties representing inappropriate patient selection exceeds 15% of the total prescriptions written, the company is required to report such to the FDA and further required to conduct physician training programs for the offending specialties.
- G) In one section of the Quarterly Reports to the FDA, Cephalon simply states that no individual speciality exceeds 15%. This 15% reporting applies to specialties designated to represent appropriate patient selection as well as a dozen or more specialties representing inappropriate patient selection.
- H) In the section of Quarterly Report to the FDA corresponding to specialties representing appropriate vs. inappropriate patient selection



requirement, nothing is reported. This section is routinely omitted from the report.

I) Prescribing data is not analyzed by appropriate and inappropriate patient selection so the ratio has not been determined or reported.

J) No physician training programs for offending specialties have been conducted.

K) Not only has Cephalon not taken any action to reduce the ratio of prescriptions written by specialties representing inappropriate patient selection but Cephalon's goal is to grow the use of Actiq at an extraordinary rate.

37. Cephalon permitted the above to occur in an effort to increase the sales and profits of Cephalon to the detriment of the public.

38. At the time the plaintiff submitted the draft audit report to Mr. Sheehan, plaintiff requested of Mr. Sheehan the method by which the report was to be published.

39. Mr. Sheehan directed the plaintiff not to publish the report until Mr. Sheehan discussed the report with Mr. Kaplan.

40. The plaintiff periodically asked Mr. Sheehan for permission to distribute the report. For approximately

six weeks, Mr. Sheehan refused to grant the plaintiff permission to distribute the report, after repeated requests by plaintiff to distribute the report.

41. During the six weeks, plaintiff was waiting to publish his report Cephalon hired Mr. Armando Cortez as Director of Quality Assurance.

42. On November 10, 2003, plaintiff had decided that he was going to disclose his findings, conclusions, and RMP report to the authorities.

43. The plaintiff discussed his concerns and decision to disclose with Lisa Carle. She indicated that since Mr. Cortez had recently been hired that plaintiff not disclose the RMP audit report until Mr. Cortez had an opportunity to review plaintiff's RMP report on Actiq.

44. Plaintiff complied with Lisa Carle's request to have Mr. Cortez review the RMP report prior to publication.

45. Mr. Cortez learned of the plaintiff's discussion with Ms. Carle regarding plaintiff's desire to disclosure the RMP report on Actiq.

46. On November 11, 2003, Mr. Cortez came to plaintiff's office to discuss an unrelated audit in France. While Mr. Cortez was in plaintiff's office, plaintiff asked Mr. Cortez why plaintiff's RMP report on Actiq was being delayed in its publication.

47. Mr. Cortez gave no reasons for the delay in publishing plaintiff's RMP report.
48. As a result of plaintiff's requests, on November 13, 2003, Mr. Cortez agreed to call a meeting to discuss the report. The November 13 meeting was attended by Richard Kaplan, Mr. Cortez, Mr. Sheehan, and plaintiff. Mr. Kaplan directed the plaintiff to mark the copy, RMP report "Confidential-Do Not Copy." Mr. Kaplan also directed the plaintiff to collect the copies of the RMP report at the end of the meeting. Mr. Kaplan and Ms. Parker were concerned that the report might get into the "wrong hands." Mr. Kaplan was quite angry at the meeting.
49. At the November 13 meeting, plaintiff was given specific instructions as to who was to review the RMP report and how it was to be reviewed.
50. The meeting to review the RMP report was to take place on or about December 1, 2003.
51. The December 1 meeting participants were to be Tracie Parker, Kay McGhee and a marketing person plaintiff believed to be Dan Winkleman (he replaced Paula Castagno).
52. Ms. Parker and Mr. Winkleman attended the December 1 meeting from the beginning. Ms. McGhee was late, and

the meeting began in her absence.

53. When Ms. Parker learned the contents of the report that Cephalon was not in compliance, etc., she stated the plaintiff was not permitted to recite in the RMP report that Cephalon was not in compliance. Plaintiff responded that that was not how he was obligated to prepare his audit. Ms. Parker insisted that Ms. Parker's superior attend the meeting. Ms. Parker demanded that her name be removed from the report. Ms. Parker then said she would not participate in the meeting and left the meeting.
54. A short time later Ms. Parker returned to the meeting with Mr. Kaplan. Mr. Kaplan asked some questions then he and Ms. Parker left the meeting.
55. The December 1 meeting continued with Mr. Winkleman providing comments on marketing. As the meeting was concluding Ms. McGhee entered the meeting. The meeting then continued wherein McGhee provided comments concerning product safety.
56. Subsequent to the December 1 meeting, the plaintiff, that same day, made revisions to the RMP report, based on the comments received at the meeting of December 1.
57. On December 1, 2003, after the revisions were made by the plaintiff, the plaintiff distributed the RMP

finalized report.

58. Copies of Plaintiff's finalized RMP report on Actiq were distributed to various individuals in Cephalon and the original copy of the report was placed in the QA Audit Central Files.
59. In accordance with Cephalon's policy, Carol Marchione was responsible to coordinate the response to the RMP report on Actiq since her group was responsible for assembling and reporting the RMP data to the FDA each quarter.
60. Ms. Marchione was asked for a response target date which she selected to be the end of December 2003.
61. The response target date was moved by Ms. Marchione to the end of January 2004.
62. In the week of February 2, 2004, almost the entire Quality Assurance Department was at a QA Summit in Salt Lake City, Utah. Plaintiff was excluded from the QA Summit.
63. On February 9, 2004, plaintiff reminded Mr. Sheehan that the response to the RMP report was overdue and plaintiff sought permission from Mr. Sheehan to send Ms. Marchione a note concerning the response to the RMP report.
64. On February 9, 2004, Mr. Sheehan denied plaintiff his

request to send a reminder note to Ms. Marchione concerning the response to the RMP report.

65. From February 9, through February 12, 2004, plaintiff asked Mr. Sheehan for permission to send a reminder note to Ms. Marchione concerning the response to the RMP report. Mr. Sheehan repeatedly denied plaintiff's requests.

66. In the afternoon of February 12, 2004, Mr. Cortez directed the plaintiff to accompany him to a meeting.

67. In attendance at the February 12, 2004, meeting were Mr. Cortez and Pat Vandenberg of Human Resources.

68. At the February 12, 2004, the plaintiff was informed that he was summarily fired from his position of employment with Cephalon.

69. Plaintiff received no advance notice from the defendants of his firing.

70. Following the February 12, 2004, meeting wherein plaintiff was fired, Mr. Cortez escorted the plaintiff back to his office where plaintiff collected his personal effects; then Mr. Cortez escorted the plaintiff to the front door of Cephalon and directed the plaintiff to leave the Cephalon facility.

71. On February 12, 2004, plaintiff was offered compensation and job search assistance provided the

plaintiff "not say or do anything which is in anyway detrimental to Cephalon," that is plaintiff would forever be prevented from disclosing the RMP audit of Actiq which disclosed that Cephalon is not in compliance with FDA approvals for the drug Actiq.

72. Plaintiff did not accept Cephalon's offer of the hush money, that is, plaintiff refused to accept compensation under the terms and conditions that would silence plaintiff concerning plaintiff's RMP audit report on the drug Actiq.
73. Plaintiff is entitled, and Cephalon is obligated to pay plaintiff the compensation and benefits as recited in the proffered agreement dated February 12, 2004, signed by Mr. Carl A. Savini absent any condition that plaintiff be silenced concerning plaintiff's RMP report on Actiq.
74. Plaintiff had a duty and obligation to disclose his findings and conclusions regarding the noncompliance in question to the defendant Cephalon.
75. Plaintiff had a legal duty and obligation to disclose his findings, conclusions, and report regarding the noncompliance in question to the FDA.
76. Plaintiff's failure to report his findings, conclusions and report regarding the noncompliance in question to

the FDA would expose the plaintiff to civil and/or criminal liability for suppressing such noncompliance.

77. Plaintiff believes that the Risk Management Plan contains provisions that legally obligate plaintiff to disclose his findings, conclusions, and report regarding the noncompliance in question to the FDA.

(Plaintiff does not have a copy of the RMP and the audit report in question; and therefore, must obtain same in discovery.)

78. The named individual defendants acting in an extra-corporate purpose to protect their own careers, earnings and other remuneration, conspired to intimidate, coerce and wrongfully discharge plaintiff in an effort to prevent, hinder, and/or delay the execution of federal law by participating in a scheme (a) to fire plaintiff, (b) to prevent him from having further access to the audit report, company data and the RMP, and (c) then offering him money for his silence by requiring him to sign an Agreement for money wherein he promised "not to say or do anything which in anyway is detrimental to Cephalon," which would prohibit plaintiff from disclosing his findings, conclusions and report of non-compliance in question to the FDA and others such as agencies.



79. The conduct of the plaintiff as recited in this Complaint was protected Whistle Blowing conduct.
80. The individual defendants, Frank Baldino, Richard Kaplan, Tim Sheehan, and Armando Cortez are agents and/or employees of Cephalon and Cephalon is liable for the actions of the individual defendants as their principal master and/or employer.
81. Cephalon is liable for the conduct of the individual defendants under respondeat superior.
82. Based on that which is recited in this Complaint and other actions, on February 12, 2004, the defendants wrongfully discharged the plaintiff in violation of a clear mandate of public policy, in retaliation against the plaintiff for engaging in protected whistle blowing conduct as recited in this Complaint.
83. The individual defendants herein learned of the plaintiff's whistle blowing protected conduct and retaliated against the plaintiff and participated in the plaintiff's wrongful discharge.
84. The defendants herein acted jointly, in combination, in concert, and in conspiracy with one another, within the scope and course of their employment or their relationship with Cephalon in retaliatory action against plaintiff thereby ratifying, acquiescing,

condoning or otherwise approving the perpetuation and continuance of the retaliatory conduct, scheme and plan against plaintiff.

85. In firing the plaintiff, the defendants did not follow the policies and procedures of Cephalon in addition to violating State and Federal Law.

86. The Plaintiff's conduct as recited herein is protected conduct under State and Federal Law.

87. As a result of the direct and proximate results of defendants' intentional, malicious, willful, wanton, reckless or otherwise egregious conduct, plaintiff's State and Federal rights under law have been violated and plaintiff has suffered and will suffer damages.

88. As a result of what has been recited herein. Plaintiff has suffered the following (not by way of limitation): Lost past earnings and benefits, lost future earnings and benefits, severance pay, medical insurance coverage, pension losses, vacation time, administrative time, sick time, comp-time, anxiety, stress, embarrassment, humiliation, emotional distress, attorney's fees and costs, all of which constitute damages for which the Defendants are liable.

89. The defendants acted with wanton and wilful disregard for the rights of Plaintiff, committed evil minded

acts, and participated in intentional wrongdoing, all of which constitutes malice and subjects the Defendants to liability for punitive damages.

**WHEREFORE,** the Plaintiff seeks a judgment against the defendants Cephalon, Inc., Frank Baldino, Richard Kaplan, Tim Sheehan, Armando Cortez and John Does for:

- A) Compensatory damages;
- B) Punitive damages;
- C) Attorney's fees;
- D) Interest and costs.

**SECOND COUNT**  
**(CEPA CLAIM)**

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**[Note: This Second Count has been dismissed by Court Order. Defendants need not Answer it.]**

- 1) The First Count is repeated herein and made part of this Count.
- 2) The conduct of the plaintiff, as recited in this Complaint, was protected conduct within the meaning of the Conscientious Employee Protection Act (CEPA), N.J.S.A 34:19-2, et seq.
- 3) The defendants violated CEPA N.J.S.A 34:19-2, et seq. in wrongfully discharging plaintiff for engaging in his protected conduct as recited herein.
- 4) In the event CEPA N.J.S.A 34:19-2 applies to plaintiff's wrongful discharge, then in such event, the

plaintiff elect to proceed under CEPA N.J.S.A 34:19-2, and not under a common law claim as recited in the First Count.

**WHEREFORE,** the Plaintiff seeks a judgment against the defendants Cephalon, Inc., Frank Baldino, Richard Kaplan, Tim Sheehan, Armando Cortez and John Does for:

- A) Compensatory damages;
- B) Punitive damages;
- C) Attorney's fees;
- D) Interest and costs.

**THIRD COUNT**  
**(CONTRACT AND ERISA CLAIM)**

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- 1) The First Count is repeated herein and made part of this Count.
- 2) On February 12, 2004, plaintiff was offered compensation and job search assistance provided the plaintiff "not say or do anything which is in anyway detrimental to Cephalon," that is plaintiff would forever be prevented from disclosing the RMP audit of Actiq which discloses that Cephalon is not in compliance with FDA approvals for the drug Actiq.
- 3) Plaintiff did not accept Cephalon's offer of the hush money, that is, plaintiff refused to accept compensation under the terms and conditions that would silence plaintiff concerning plaintiff's RMP audit

report on the drug Actiq.

- 4) Plaintiff is entitled, and Cephalon is obligated to pay plaintiff the compensation and benefits as recited in the proffered agreement dated February 12, 2004, signed by Mr. Carl A. Savini absent any condition that plaintiff be silenced concerning plaintiff's RMP report on Actiq.
- 5) As part of his employment contract, the plaintiff is entitled to severance pay and other benefits due to his being fired by Cephalon.
- 6) It is the policy and practice of Cephalon to provide severance pay and other benefits to terminated employees.
- 7) Plaintiff was denied severance pay and other benefits upon his firing on February 12, 2004.
- 8) The defendant Cephalon asserted that the plaintiff's compensation and benefits which plaintiff was to receive upon termination is regulated by the Employee Retirement Income Security Act (ERISA) under a plan adopted by Cephalon. (Plaintiff would need discovery as to Cephalon's ERISA representations.)
- 9) In the alternative, plaintiff is entitled and Cephalon is obligated to pay plaintiff the compensation and benefits in question upon his termination in accordance

with the ERISA and Cephalon's plan

**WHEREFORE,** the Plaintiff seeks a judgment against the defendants Cephalon, Inc., Frank Baldino, Richard Kaplan, Tim Sheehan, Armando Cortez and John Does for:

- A) Compensatory damages;
- B) Punitive damages;
- C) Attorney's fees;
- D) Interest and costs.

**FOURTH COUNT**  
**(TORT ACTION)**

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**[Note: This Fourth Count has been dismissed by Court Order. Defendants need not Answer it.]**

- 1) The First Count and Third Counts are repeated herein and made part of this Count.
- 2) The defendants offer of compensation and benefits to plaintiff in return for his silence concerning the defendants wrongful conduct is illegal and against public policy.
- 3) In the past, the defendant Cephalon has taken a similar approach to employees who possessed detrimental information regarding Cephalon, thus engaging in a pattern of such conduct to silence Cephalon employees.
- 4) The defendants acted with wanton and wilful disregard for the rights of Plaintiff, committed evil minded acts, and participated in intentional wrongdoing, all

of which constitutes malice and subjects the Defendants to liability for punitive damages.

**WHEREFORE**, the Plaintiff seeks a judgment against the defendants Cephalon, Inc., Frank Baldino, Richard Kaplan, Tim Sheehan, Armando Cortez and John Does for:

- A) Compensatory damages;
- B) Punitive damages;
- C) Attorney's fees;
- D) Interest and costs.

**FIFTH COUNT**

**[Note: This Fifth Count has been dismissed by Court Order. Defendants need not Answer it.]**

- 1) The First Count through the Fourth Count is incorporated by reference and made a part of this Count.
- 2) The plaintiff's complaints, statements, communications, whistle blowing actions, etc. as recited herein, are protected conduct by the United States Constitution First Amendment, U.S.C.A. Const. Amends 1 & 14.
- 3) The defendants conspired, intimidated, coerced and wrongfully discharged the plaintiff for exercising his First Amendment rights and engaging in the protected conduct as recited herein.
- 4) The plaintiff's complaints, statements, communications, and whistle blowing actions etc., are protected conduct

under Section 2 of the Civil Rights Act of 1871, 42  
U.S.C. §1985.

- 5) The defendants have conspired to "prevent hinder or delay the execution of federal law" which is in violation of Section 2 of the Civil Rights Act of 1871; U.S. Congress Statutes at Large, Vol XVII, Ch 22, Section 2 (Approved April 20, 1871); 42 USC § 1985.
- 6) The defendants conspired to wrongfully discharge the plaintiff for the complaints, statements, communications, and whistle blowing activities etc. recited herein wherein the defendants' actions were in violation of, Section 2 of the Civil Rights Act of 1871, to coerce and intimidate the plaintiff regarding his right to make the statements and disclosures to the public and Federal authorities as recited in this Complaint.

**WHEREFORE**, the plaintiff seeks a judgment against the defendants Cephalon, Inc., Frank Baldino, Richard Kaplan, Tim Sheehan, Armando Cortez and John Does for:

- A) Compensatory damages;
- B) Punitive damages;
- C) Attorney's fees; and
- D) Interest and costs.

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**JURY TRIAL DEMAND**



Plaintiff hereby demands a trial by jury as to all issues.

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